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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/921,533	09/02/1997	PERTTI TORMALA	2880/27	9610

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NEW YORK, NY 10004

EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/921,533

Applicant(s)

TORMALA ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Upon careful consideration of the finality of the rejection of the last Office action has been withdrawn and the following new rejection is applied to the instant claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 and 9-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent 6,406,498 ('498) in view of US 4,743,257 ('257) and US 4,778,471 ('471). Although the conflicting claims are not identical, they are not patentably distinct from each other because '498 teach bioactive, bioabsorbable surgical composite material comprising a bioabsorbable polymer matrix that is oriented and bioactive glass or ceramic particles dispersed in the matrix that is self-reinforced, wherein said particles extend at least into said pores. Thus, the self-reinforced polymeric matrix of '498 reads on the instant composite material having a resorbable matrix, a reinforcing component mixed with said matrix component and a bioglass component in the form of particles. '498 claims particle sizes but fails to claim the specific particle size of 60 to 150 microns. '498 also fail to specify the process steps for preparing the composite material and fiber diameters, a claimed.

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'257 teach a self-reinforced surgical osteosynthesis composite material formed by an absorbable polymer or copolymer matrix, which is reinforced with the absorbable reinforcement units and which have the same chemical element percentage composition as the matrix (col. 3-4). With respect to the method of manufacturing, '257 teach mixing together a melt of the absorbable polymer or copolymer and subjecting to heat and pressure (examples and claim 12). '257 teach the same polymeric materials such as those claimed in the instant claim 13 for preparing the matrix and the reinforcing element (examples). Figure 1 of '257 shows the arrangement of the polymeric matrix and reinforcing fibers in the surgical composite material.

'471 teach zinc based ceramic materials that can be used in same applications as hydroxyapatite and other ceramic materials, and used for surgical applications. '471 teach particulate ceramic materials that have particle size of about 1 to 400 microns. '471 teach that for a bone implant device, a particle size of 40 to 200 microns can be used and for drug delivery a particle size of 1 to 38 microns (col. 3, lines 8-16). '471 also teach that the ceramic particles are mixed antibiotics for treating any infection, or hormones, proteins etc (Col. 4 and col. 5). '471 teach delivering the substances from the ceramics by impregnating ceramics with the various polymeric materials (lines bridging cols 4 through col. 5) for successful resorption of ceramic within the body (col. 5).

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare a bone composite material of '498 employing the process of steps of '257 because '257 teaches that manufacturing the composite materials by the application of heat and pressure results in self-reinforced bioabsorbable materials that have high content of oriented fibers, smooth surface, low porosity and good strength. Further, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ bioglass or ceramic particles, in an appropriate particle size range in the surgical composite material of '498

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depending on the use of ceramic particles as a cement or for drug delivery, because '471 suggests specific particle sizes for either purposes (cement or drug delivery) and suggests that increase in particle size is associated with a decrease in mechanical strength and an increase in porosity. Accordingly optimizing the particle size with an expectation to achieve the desired porosity and mechanical strength of the composite material would have been within the scope of a skilled artisan. Further, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to incorporate a suitable pharmaceutical such as hormone, antibiotic, etc., depending on the treatment because '471 teaches that the success of the implant depends on the ability of ceramic to resorb in the body and also on the type of drug to be delivered. With respect to the claimed volume fraction of the bioglass, absent unexpected results, '471 recognizes various ceramic materials (col. 2) and their particle sizes that are suitable for implant as well as drug delivery purposes and accordingly optimizing the volume of ceramic particles in the implant or composite material of '498 would have been within the scope of a skilled artisan.

Response to Arguments

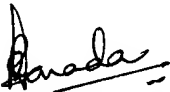
Applicants' arguments filed on 1-17-06 have been considered but are moot in view of new grounds of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615
April 17, 2006



THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600